

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

SARA E. ANDERSON, personal
representative for the Estate of
Sharon M. Davis,

Plaintiff,

v.

Case No. 6:20-cv-2393-WWB-GJK

JOHNSON & JOHNSON and
ETHICON, INC.,

Defendants.

REPORT AND RECOMMENDATION

This cause came on for consideration without oral argument on the
following motion:

**MOTION: DEFENDANTS' MOTION TO DISMISS
PLAINTIFF'S SECOND AMENDED COMPLAINT
AND INCORPORATED MEMORANDUM OF LAW
(Doc. No. 39)**

FILED: April 21, 2021

**THEREON it is RECOMMENDED that the motion be GRANTED
in part and DENIED in part.**

I. BACKGROUND.

On December 30, 2020, Plaintiff Sara E. Anderson filed a Complaint against Defendants Johnson & Johnson (“J&J”) and Ethicon, Inc. (“Ethicon”) (collectively, “Defendants”)¹ for injuries suffered by Plaintiff’s decedent, Sharon M. Davis, related to the implantation of Ethicon’s Gynecare TVT-Obdurator (“TVT-O”) pelvic mesh product on October 29, 2004, and the subsequent revision surgery/removal of the TVT-O and implantation of Ethicon’s Gynecare TVT-Abbrevio (“TVT-A”) (collectively, the “TVT products”) on August 7, 2015 after Davis developed complications. Doc. No. 1.

On April 7, 2021, Plaintiff filed a Second Amended Complaint.² Doc. No. 34. Plaintiff alleges causes of action for: negligence, strict liability-design defect, strict liability-manufacturing defect, strict liability-failure to warn, breach of express warranty, breach of implied warranty, fraudulent concealment, common law fraud, constructive fraud, negligent misrepresentation, negligent infliction of emotional distress, and unjust enrichment. Doc. No. 34.

Plaintiff alleges that Defendants sell the TVT products, which are pelvic mesh designed to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”) in women. *Id.* at ¶¶ 14, 15. The TVT products were approved

¹ Ethicon is wholly owned by J&J. Doc. No. 34 at ¶ 9.

² At this stage of the proceedings, the facts alleged in the Second Amended Complaint are taken as true.

under an abbreviated 510(k) approval process because they were deemed substantially equivalent to other predicate surgical mesh products. *Id.* at ¶22. This abbreviated process did not require Defendants to prove the safety or efficacy of the TVT products through the FDA's formal review process. *Id.* at ¶ 23.

The TVT products contain materials, polypropylene and collagen, that are biologically incompatible with human tissue, creating an immune response which in turn promotes degradation of the mesh and the surrounding pelvic tissue, which can contribute to severe adverse reactions to the mesh including shrinkage or contraction of the mesh, nerve entrapment, inflammation, chronic infectious response, chronic pain, and urinary dysfunction. *Id.* at ¶¶ 16, 18, 19, 20, 61. Defendants were on notice as early as October 2008 about potential risks posed by the TVT products. *Id.* at ¶ 29. The Food and Drug Administration ("FDA") issued numerous notices and warnings about the dangers of pelvic mesh products, as did several medical associations and consumer advocacy groups. *Id.* at ¶¶ 29-36, 37-39. Despite multiple sources of concern and warnings about related products, as well as the TVT products, Defendants continued to market, distribute, and sell TVT products to healthcare providers and their patients while minimizing the risk of serious complications. *Id.* at ¶¶ 48, 53, 54, 55, 56, 57.

Plaintiff claims Defendants withheld, omitted, or misrepresented this information to Davis, Davis's medical providers, the medical community, the

FDA, and the public at large. *Id.* at ¶¶ 18, 19, 20, 48, 53, 56. Davis and her implanting physicians justifiably relied upon Defendants' misrepresentations, Davis and her physicians were unaware of the problems with the TVT products, and had they been aware, they would not have acted as they did. *Id.* at ¶¶ 56, 57, 58, 59. Defendants marketed the TVT products to Davis's physicians' office through sales representatives that visited the physicians' office both before and after Davis's implantation procedures and advised that the TVT products were "safe and effective," "do not cause chronic conditions," and "do not degrade or otherwise deform." *Id.* at ¶ 59.

Davis developed complications from the implant of the TVT-O, including worsening stress urinary incontinence, pain with sexual intercourse, vaginal bleeding and irritation. *Id.* at ¶ 5. Davis then underwent revision surgery and the removal of the TVT-O and implantation of the TVT-A, but continued to suffer from worsening incontinence, pelvic pain, dyspareunia, and several emotional distress. *Id.* at ¶ 7.

On April 21, 2021, Defendants filed a Motion to Dismiss the Second Amended Complaint (the "Motion"). Doc. No. 39. In the Motion, Defendants argue that Plaintiff still fails to plead sufficient facts to support her causes of action.³ *Id.* Defendants seek dismissal of Plaintiff's claims for: design defect,

³ Defendants also argued that the statute of repose barred Plaintiff's claims regarding the implant

manufacturing defect, and failure to warn because she fails to state a claim; negligence based on the failure to properly plead design defect, manufacturing defect, and failure to warn; negligent infliction of emotional distress based on Plaintiff's failure to plausibly plead a physical injury; express or implied warranty for failure to allege privity and identify the statements made, instead making conclusory factual allegations; fraud and misrepresentation as repackaged failure to warn claims and because they lack the requisite particularity; and unjust enrichment for failure to allege an inequitable transfer of wealth and Plaintiff cannot claim she lacks a legal remedy. *Id.*

On April 21, 2021, Plaintiff filed a response to the Motion (the "Response") arguing that she has sufficiently pled each count for purposes of a motion to dismiss. Doc. No. 39. On May 21, 2021, as authorized by the Court, Defendants filed a reply to the Response (the "Reply"). Doc. Nos. 46, 47. Defendants argue that Plaintiff fails to satisfy the privity requirement for her warranty claims under the "substantial direct contacts" test or other exception. *Id.* at 1-3. Defendants also argue that Plaintiff is not exempt from the particularity requirements of Rule 9(b). *Id.* at 3-4.

of Defendants' product in 2004, but Defendants have withdrawn that argument. Doc. No. 47 at 1.

II. STANDARD OF REVIEW.

“When considering a motion to dismiss for failure to state a claim, a court must accept the allegations in the complaint as true, construing them in the light most favorable to the plaintiff.” *Murphy v. F.D.I.C.*, 208 F.3d 959, 962 (11th Cir. 2000) (citing *Kirby v. Siegelman*, 195 F.3d 1285, 1289 (11th Cir. 1999)). The Court is limited to reviewing what is within the four corners of the complaint. *St. George v. Pinellas Cty.*, 285 F.3d 1334, 1337 (11th Cir. 2002).

A complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief[.]” Fed. R. Civ. P. 8(a)(2). This standard does not require detailed factual allegations, but does demand “more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Specifically, the factual allegations, accepted as true, must “state a claim to relief that is plausible on its face.” *Id.* (quoting *Twombly*, 550 U.S. at 570). This cannot be achieved through mere legal conclusions or recitation of the elements of a claim. *Id.* (citing *Twombly*, 550 U.S. at 555).

Instead, to state a plausible claim for relief, the plaintiff must go beyond merely pleading the “sheer possibility” of unlawful activity by a defendant and offer “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at

556). “Conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts will not prevent dismissal.” *Davilia v. Delta Air Lines, Inc.*, 326 F.3d 1183, 1185 (11th Cir. 2003). If the plaintiff fails to meet this pleading standard, then the complaint will be subject to dismissal pursuant to Federal Rule of Civil Procedure 12(b)(6).

III. ANALYSIS.

As an initial matter, the Court would observe that while the Second Amended Complaint is not a textbook shotgun pleading, in that each count does not incorporate all preceding counts into subsequent counts, the Second Amended Complaint presents a similar problem to that of a shotgun pleading. Each count begins with a general allegation that each “material fact” contained in the complaint is incorporated into each of the twelve counts presented.⁴ Doc. No. 34 at ¶¶ 83, 104, 112, 116, 141, 157, 169, 191, 211, 227, 247, 259. The method of pleading presents several problems. It attempts to make the Court, rather than Plaintiff, the arbiter of what facts are material to each count and where those facts can be found anywhere throughout the Second Amended Complaint. In *Beckwith v. Bellsouth Telecommunications Inc.*, 146 F. App’x 368, 372 (11th Cir. 2005), the district court did

⁴ See *Merino v. Ethicon Inc.*, No. 20-25308-CIV, 2021 WL 1749967, at *3 (S.D. Fla. May 4, 2021) (rejecting argument that complaint was a shotgun pleading because “Plaintiff ‘incorporates by reference each and every material fact of this Complaint as if fully set forth herein[.]’” and thus incorporated only the material facts, and not the preceding counts, into every count).

not abuse its discretion in requiring the plaintiff to file a more definite statement where, among other things, “the relevant facts were not segregated to each of their respective claims.”⁵ In a case such as this with a pleading containing 269 paragraphs involving twelve counts and facts which may or may not be viewed as material interspersed throughout those paragraphs as well as various counts, the Second Amended Complaint denies the Court and Defendants of clarity regarding the facts supporting each claim and, therefore, frustrates analysis of the Motion. The Court and Defendants are not required to “sift through the facts presented and decide for [themselves] which were material to the particular cause of action asserted.” *Id.* (quoting *Strategic Income Fund, L.L.C. v. Spear, Leeds & Kellogg Corp.*, 305 F.3d 1293, 1296 n. 9 (11th Cir.2002) (citations omitted)).

The Second Amended Complaint also violates Federal Rule of Civil Procedure 8, which requires a short plain statement of the claim. “The statement must ‘give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.’” *Schambeau v. Schambeau*, No. CV 20-0436-TFM-MU, 2021 WL 667927, at *7 (S.D. Ala. Jan. 21, 2021), *report and recommendation adopted*, No. 1:20-CV-436-TFM-MU, 2021 WL 665104 (S.D. Ala. Feb. 19, 2021) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. at 555, (2007) (quotation omitted) (ellipses in original)).

⁵ In this circuit, “[u]npublished opinions are not considered binding precedent, but they may be cited as persuasive authority.” 11th Cir. R. 36-2.

Incorporating all preceding “material facts” fails to provide the grounds upon which the claim rests.

Plaintiff identified the relevant paragraphs of the Second Amended Complaint, with the related material facts, in her Response, Doc. No. 44 at 5, so there is no reason she cannot do so in any future amendment. As such, any amendment should properly and specifically identify which material factual allegations relate to each cause of action.

A. Counts I and XI: Negligence and Negligent Infliction of Emotional Distress

Plaintiff states a negligence claim against Defendants. Under Florida law, a plaintiff must allege that the defendant owed a duty, that the defendant breached that duty, and that this breach caused the plaintiff damages. *Fla. Dep’t of Corr. v. Abril*, 969 So. 2d 201, 204-05 (Fla. 2007). “The duty element of negligence focuses on whether the defendant’s conduct foreseeably created a broader ‘zone of risk’ that poses a general threat of harm to others.” *McCain v. Fla. Power Corp.*, 593 So. 2d 500, 502 (Fla. 1992). Where a product is alleged to be defective “and that defect rises to the level of a dangerous condition, the manufacturer or designer has created a zone of risk to all parties who may come in contact with the product.” *Stazenski v. Tennant Co.*, 617 So. 2d 344, 346 (Fla. 1st DCA 1993). Thus, the manufacturer of a product has “a duty to use reasonable care to design a product that is reasonably safe for its intended use and for other uses which are foreseeably

probable.” *Brandt v. Depuy Orthopaedics, Inc.*, No. 6:10-cv-306, 2010 U.S. Dist. LEXIS 63892, at *9 (M.D. Fla. June 28, 2010) (quoting *Vincent v. C.R. Bard, Inc.*, 944 So. 2d 1083, 1085 (Fla. 2d DCA 2006) (internal quotation omitted)).

Plaintiff alleges Defendants had a duty to use reasonable care in designing, researching, manufacturing, marketing, labeling, packaging, supplying, distributing, and selling the TVT products and failed to inspect and test the products before releasing and marketing them to Davis and other consumers. Doc. No. 34 at ¶¶ 22-26, 42, 49, 63, 65, 85. Plaintiff alleges that the TVT products have high rates of failure, injury, and complications, fail to perform as intended, require frequent reoperations, and have caused severe and irreversible injuries to a significant number of women, making them defective under the law. *Id.* at ¶¶ 60-61, 84. Plaintiff alleges that Davis was injured and suffered similar complications after implantation of the TVT products, including the need for revision surgery after implantation of the TVT-O. *Id.* at ¶¶ 4, 5, 7. Thus, Plaintiff sufficiently alleges Defendants breached their duty and caused harm to Davis. *Id.* at ¶¶ 60-61, 85-86.

Defendants argue that Plaintiff fails to state a claim for negligent infliction of emotional distress because she has not plausibly pled that Davis incurred a physical injury. Doc. No. 39 at 14.

In Florida, the prerequisites for recovery for negligent infliction of emotional distress differ depending on whether the plaintiff has or has not suffered a physical impact from an external force. If the plaintiff has suffered an impact, Florida

courts permit recovery for emotional distress stemming from the incident during which the impact occurred, and not merely the impact itself. If, however, the plaintiff has not suffered an impact, the complained-of mental distress must be “manifested by physical injury,” the plaintiff must be “involved” in the incident by seeing, hearing, or arriving on the scene as the traumatizing event occurs, and the plaintiff must suffer the complained-of mental distress and accompanying physical impairment “within a short time” of the incident. When plaintiffs suffer an impact, they are permitted to recover for the emotional distress that flows from the impact.

Willis v. Gami Golden Glades, LLC, 967 So. 2d 846, 850 (Fla. 2007) (quoting *Eagle-Picher Indus., Inc. v. Cox*, 481 So. 2d 517, 526 (Fla. 3d DCA 1985)). Thus, a plaintiff can recover for negligent infliction of emotional distress if “one experiences a physical impact during the incident and suffers emotional distress suffering from that incident.” *Seybold v. Clapis*, 966 F. Supp. 2d 1312, 1315 (M.D. Fla. 2013).

Plaintiff alleges Davis suffered physical injuries and severe emotional distress from the implantation of the TVT products and that she also experienced pain and suffering that were caused by the psychological trauma (stress, anxiety, sadness, anger, etc.). Doc. No. 34 at ¶¶ 5, 7, 255. Plaintiff alleges Davis’s emotional distress was medically diagnosable. *Id.* at ¶ 256. The Court finds Plaintiff has plausibly pled a claim for negligent infliction of emotional distress as she was subject to physical injuries from an impact (the implantations) and suffered emotional distress flowing from those injuries.

Defendants argue Plaintiff's negligence claims should be dismissed to the extent the underlying theories of design defect, manufacturing defect, and failure to warn are dismissed. The Court will not "strike alleged duties from the Complaint[] in line-item fashion." *Merino*, 2021 U.S. Dist. LEXIS 84942, at *14; *see also Havana Docks Corp. v. Carnival Corp.*, No. 19-cv-21724, 2020 U.S. Dist. LEXIS 167216, 2020 WL 5517590, at *12 (S.D. Fla. Sept. 14, 2020) ("[C]ourts routinely refuse to excise 'in line-item fashion' portions of a complaint where the claim at hand is otherwise adequately stated." (alteration added; citations omitted)). For the reasons explained in sections III. B. and III. D., *infra*, Plaintiff sufficiently alleges negligence and negligent infliction of emotional distress claims based on design defect and failure to warn theories, alleging Defendants had a duty to use reasonable care in designing the TVT products or ensuring adequate warnings were provided to treating physicians.

B. Count II : Design Defect

Defendants argue that Plaintiff fails to sufficiently identify any design defects and she fails to plead facts that plausibly show her injuries were caused by the alleged defects. Doc. No. 39 at 6. Instead, Defendants argue that Plaintiff offers only vague and conclusory allegations and fails to identify which defective propensities of the TVT-O necessitated a revision procedure, and which supposed defects of either product caused her to suffer injuries after her TVT-A

implantation. *Id.* at 6-7.

“To state a claim in Florida for strict products liability based on a design or manufacturing defect, a plaintiff must plead three elements: (1) a relationship between the defendant and the product; (2) a defect which caused the product to be unreasonably dangerous; and (3) causation between the defect and the harm suffered by the user.” *Dye v. Covidien LP*, 470 F. Supp. 3d 1329, 1334 (S.D. Fla. 2020) (internal quotation marks and citations omitted). “The complaint must contain factual allegations about what was in fact defective about the product.” *Merino v. Ethicon Inc.*, 2021 U.S. Dist. LEXIS 84942, at *15 (S.D. Fla. May 4, 2021) (quoting *Shapiro v. NuVasive, Inc.*, No. 19-23163-Civ, 2019 U.S. Dist. LEXIS 191373, 2019 WL 5742159, at *2 (S.D. Fla. Nov. 5, 2019) (internal quotation marks and citations omitted). Courts have recognized, however, that it is difficult at the pleading stage to know the source of the defect that was responsible for the harm caused, thus Florida law “does not require that a plaintiff specifically set out the type of defect (design, manufacturing, or failure to warn) at the pleading stage.” *Brandt*, 2010 U.S. Dist. LEXIS 63892, at *7 (citing *Bailey v. Janssen Pharmaceutica*, 288 F. App’x 597, 605-06 (11th Cir. 2008)); see *Merino*, 2021 U.S. Dist. LEXIS 84942, at *19 (“[u]nder Florida law, plaintiffs are not required to set forth the precise chemical, biological, or other process by which the defective product causes the alleged harm [to defeat] a motion to dismiss”) (quoting *Dye*, 470 F. Supp. 3d at 1366).

Plaintiff identifies multiple issues with the design of the TVT products in the Second Amended Complaint, including: 1) problems with the materials used; 2) biomechanical issues with the design; 3) use and design of the arms of the implants; and 4) the propensity for degradation and fragmentation over time. Doc. No. 34 at ¶¶ 18-20, 32, 38, 45, 58-59, 61, 105. Plaintiff alleges that these and other defective propensities caused Davis's injuries and necessitated a revision procedure and resulted in additional injuries after implantation of the TVT-A. *Id.* at ¶¶ 5, 7, 56, 57-58, 61-62, 108-110. Plaintiff also alleges that the FDA has issued advisory warnings about this class of products that confirm such complications. *Id.* at ¶¶ 29-36, 37-39. Thus, Plaintiff sufficiently alleges both design defect and causation. *See Merino*, 2021 U.S. Dist. LEXIS 84942, at *19.

C. Count III: Manufacturing Defect

Defendants argue that Plaintiff fails to allege a cause of action for manufacturing defect because she fails to allege how the TVT products implanted in Davis deviated from manufacturing specifications. Doc. No. 39 at 9. "To prove a manufacturing defect claim under Florida law, a plaintiff must prove that 1) the product was defective, 2) the defect existed at the time the product left the defendant-manufacturer's control, and 3) the defect proximately caused the plaintiff's injuries." *Salinero v. Johnson & Johnson*, 400 F. Supp. 3d 1334, 1343-44 (S.D. Fla. 2019). "As distinguished from a design defect claim, a claim for

manufacturing defect is based on ‘aberrational’ defects and not those that occur throughout an entire line of products.” *Ocasio v. C.R. Bard, Inc.*, No. 8:13-cv-1962-T-36AEP, 2015 WL 3496062, at *7 (M.D. Fla. June 3, 2015) (citing *Benitez v. Synthes, Inc.*, 199 F. Supp. 2d 1339, 1344 (M.D. Fla. 2002); see *Harduvel v. Gen. Dynamics Corp.*, 878 F.2d 1311, 1317 (11th Cir. 1987) (“the distinction is between an unintended configuration, and an intended configuration that may produce unintended and unwanted results”). Thus, manufacturing defects are “generally limited to situations where something goes wrong in the manufacturing process.” *Salinero*, 400 F. Supp. 3d at 1344.

Plaintiff alleges that the TVT products “were defective as described herein as a matter of law with respect to their manufacture, in that they deviated materially from [Defendants’] design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm” to Davis. Doc. No. 34 at ¶ 113. Plaintiff then claims that as a direct and proximate result of this deviation from the design and manufacturing specifications, Davis experienced injuries. *Id.* at ¶ 114. No factual allegations support this claim of a deviation from manufacturing specifications and, unlike the factual support for the design defect claim, Plaintiff fails to offer *any* factual allegations aside from conclusory statements regarding Defendants’ deviation from its own manufacturing specifications; in fact, there are no allegations related to what those manufacturing

specifications might have been. As such, Plaintiff fails to state a claim for strict liability manufacturing defects. *See Merino*, 2021 U.S. Dist. LEXIS 84942, at *21-22. Thus, it is recommended that Count III be dismissed.

D. Count IV: Failure to Warn

Defendants argue that Plaintiff alleges risks for injuries Davis did not suffer. Doc. No. 39 at 11. Defendants also argue that the TVT products' Instructions for Use expressly warn of the risk of the types of injuries Davis experienced and Plaintiff does not explain why such warnings were inadequate. *Id.* at 12. Finally, Defendants argue that Plaintiff fails to plead facts that would plausibly show how Davis's injuries were proximately caused by any alleged warning defects. *Id.* at 13.

On a failure to warn claim, a plaintiff must allege the product warning was inadequate, the inadequate warning proximately caused her injury, and that plaintiff suffered an injury in fact from using the product. *Salinero*, 995 F.3d at 964; *Dye*, 470 F. Supp. 3d at 1338. Because Florida recognizes the learned intermediary doctrine, when a physician is involved "the duty to warn flows from the medical product manufacturer to the physician, not the ultimate consumer, and plaintiff must assert the warnings given to [the] physician were inadequate." *Dye*, 470 F. Supp. 3d at 1338. However, the "causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had substantially

the same knowledge as an adequate warning from the manufacturer should have communicated to him.” *Dimieri v. Medicis Pharms. Corp.*, No. 2:14-cv-176, 2014 U.S. Dist. LEXIS 164182, at *7 (M.D. July 14, 2014) (quoting *MacMorris v. Wyeth, Inc.*, 2:04-cv-596, 2005 U.S. Dist. LEXIS 46657, 2005 WL 1528626, at *2 (M.D. Fla. June 27, 2005)). Thus, a plaintiff must allege both 1) the physician received an inadequate warning; and 2) the physician lacked independent knowledge of the risks associated with the product. See *Dimieri v. Medicis Pharms. Corp.*, No. 2:14-cv-176, 2015 U.S. Dist. LEXIS 44174, at *6 (M.D. Fla. Apr. 3, 2015) (citing *Christopher v. Cutter Labs, Inc.*, 53 F.3d 1184, 1192 (11th Cir. 1995)).

Plaintiff alleges that Defendants provided incomplete, insufficient, and misleading training to physicians. Doc. No. 34 at ¶ 53. Specifically, she alleges that Defendants provided inadequate warnings to both Davis and her implanting physicians regarding numerous risks, including, among other things: the TVT products’ propensities to contract, retract and/or shrink; the propensities for degradation and fragmentation; the risk of chronic inflammation, infections, and pain; the need for corrective or revision surgery, the risk of de novo urinary dysfunction, dyspareunia, or painful sexual relations. *Id.* at ¶¶ 18-20, 58-59, 87-89, 117-19. Further, the TVT products’ Instructions for Use Defendants provided to Davis’s implanting physicians were deficient for failure to disclose these risks and other adverse events. *Id.* at ¶¶ 122-25. Davis’s implanting physicians relied

on these defective warnings and the Instructions for Use, *id.* at ¶ 56, the physicians did not have independent knowledge of these risks or the magnitude thereof, *id.* at ¶ 55, the physicians would have changed their consent procedures if they did, and Davis would not have consented to the implantation of the TVT products if she had been informed of all known relevant risks, adverse events, and contraindications of the TVT products, *id.* at ¶¶ 128, 133-35. As a direct and proximate result of Defendants' failure to warn, Davis suffered injuries, including worsening stress urinary incontinence, pain with sexual intercourse, vaginal bleeding and irritation, pelvic pain, dyspareunia, and several emotional distress. *Id.* at ¶¶ 5, 7, 139.

Plaintiff has plausibly alleged a cause of action for failure to warn as she has alleged Defendants' warnings to her implanting physicians were inadequate, that the physicians lacked independent knowledge of the risks, and that there was a causal link between the inadequate warnings and Davis's injuries. *See Douse v. Boston Sci. Corp.*, 314 F. Supp. 3d 1251, 1260-61 (M.D. Fla. 2018).

E. Counts V and VI: Breach of Express and Implied Warranty

Defendants argue that Plaintiff fails to sufficiently allege privity to support causes of action for breach of express or implied warranty and that Plaintiff fails to identify "a single statement or conduct that gives rise to an express or implied warranty." Doc. No. 39 at 15.

Privity of contract is required for a breach of warranty claim. *Weiss v. Gen. Motors LLC*, 418 F. Supp. 3d 1173, 1182 (S.D. Fla. 2019). Florida law recognizes that a third party may enforce the terms of a contract if the contract “primarily and directly” benefits the third party or a class of persons of which the third party is a member. *Id.* However, beyond the benefit conveyed, the requisite privity is also determined by the nature of the contact between the seller and the third party, with some courts requiring substantial direct contact between the third party and the seller. *See Douse*, 314 F. Supp. 3d at 1262 (discussing the outer boundaries of privity and finding that substantial direct contacts is required for a third party to allege privity, and product labeling, websites, and advertising are not enough) (comparing *Cedars of Lebanon Hosp. Corp. v. European X-Ray Distribs. of Am., Inc.*, 444 So. 2d 1068 (Fla. 3d DCA 1984) with *Smith v. Wm. Wrigley Jr. Co.*, 663 F. Supp. 2d 1336, 1343 (S.D. Fla. 2009)).

Plaintiff alleges that Davis purchased the TVT products from authorized physicians who purchased the products from Defendants for her benefit, and that she relied on the warranties provided therewith, including express warranties provided in the Instructions for Use, pamphlets, and commercial documents. Doc. No. 34 at ¶¶ 122, 126-28, 130, 152, 164-65.

Plaintiff also alleges that Defendants made several express and implied assurances that the TVT products were safe and fit for their intended use including

that: 1) the TVT products were safe and effective; 2) the TVT products do not contract, shrink, or otherwise deform; 3) the TVT products do not degrade; 4) the products may cause only transient or temporary injuries; and 5) the TVT products were permanent implants that would permanently resolve Davis's incontinence and would not need to be removed. Doc. No. 34 at ¶¶ 57, 77, 144, 148, 154, 161. Plaintiff also alleges that the TVT products' Instructions for Use contained these representations as well. *Id.* at ¶¶ 122, 126-28, 130. Despite this, Plaintiff fails to sufficiently allege substantial direct contact with Defendants. *See Douse*, 314 F. Supp. 3d at 1262 (dismissing third party warranty claims where the only contacts alleged between Douse and her doctors took place through product brochure, website, and advertisements). As such, it is recommended Counts V and VI be dismissed.

F. Counts VII, VIII, IX, and X: Fraud and Misrepresentation Claims

Plaintiff alleges claims for fraudulent concealment, common law fraud, constructive fraud, and negligent misrepresentation. Doc. No. 34 at 51-68. Defendants argue that Plaintiff's fraud and misrepresentation claims are nothing more than "repackaged failure-to-warn claims." Doc. No. 39 at 16. Defendants also argue that Plaintiff fails to meet the heightened pleading standard of Federal Rule of Civil Procedure 9(b). *Id.* Defendants relatedly argue that, even if the relaxed pleading standard for fraud applies, Plaintiff still fails to sufficiently allege

facts to support her causes of action for fraud and misrepresentation. *Id.* at 18-19.

To state a claim for fraud, a plaintiff must allege “(1) a false statement concerning a material fact; (2) the representor’s knowledge that the representation is false; (3) an intention that the representation induce another to act on it; and (4) consequent injury by the party acting in reliance on the representation.” *Butler v. Yusem*, 44 So. 3d 102, 105 (Fla. 2010). Fraudulent concealment is similar to actual fraud except that the defendant conceals facts instead of misrepresents them. *Kish v. A.W. Chesterton Co.*, 930 So. 2d 704, 707 (Fla. 3d DCA 2006). “[C]onstructive fraud occurs when a duty under a confidential or fiduciary relationship has been abused or where an unconscionable advantage has been taken.” *Razi v. Razavi*, No. 5:12-cv-80, 2012 U.S. Dist. LEXIS 187072, at *34 (M.D. Fla. Dec. 13, 2012) (quoting *Amer. Honda Motor Co. v. Motorcycle Info. Network, Inc.*, 390 F. Supp. 2d 1170, 1179 (M.D. Fla. 2005)). A plaintiff seeking to establish negligent misrepresentation must plead: (1) misrepresentation of a material fact; (2) made without knowledge as to its truth or falsity, or under circumstances in which its falsity should have been known; (3) the representor intended the misrepresentation induce another to act on it; and (4) injury to the party acting in justifiable reliance on the misrepresentation. *Douse*, 314 F. Supp. 3d at 1263-64 (quoting *Souran v. Travelers Ins. Co.*, 982 F.2d 1497 (11th Cir.1993) (quoting *Hoon v. Pate Constr. Co., Inc.*, 607 So.2d 423, 427 (Fla. 4th DCA1992)). However, a negligent misrepresentation claim

fails if an investigation by the recipient of the information would have revealed the falsity of the communication. *Id.* at 1264 (citing *Gilchrist Timber Co. v. ITT Rayonier, Inc.*, 696 So. 2d 334, 339 (Fla. 1997)). “In other words, a recipient of an erroneous representation cannot ‘hide behind the unintentional negligence of the misrepresenter when the recipient is likewise negligent in failing to discover the error.’” *Id.* (citing *Butler*, 44 So. 3d at 105 (citations omitted)).

Pursuant to Rule 9(b), a party alleging fraud must “state with particularity the circumstances constituting fraud[.]” Fed. R. Civ. P. 9(b). To satisfy Rule 9(b), a complaint must allege facts about the “time, place, and substance of the defendant’s alleged fraud, specifically the details of the defendants’ allegedly fraudulent acts, when they occurred, and who engaged in them.” *Gergenti v. Ethicon, Inc.*, No. 2:20-cv-428, 2020 U.S. Dist. LEXIS 173539, at *5 (M.D. Fla. Sept. 22, 2020) (quoting *U.S. ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1222 (11th Cir. 2012) (internal quotation marks omitted)). “This requires the plaintiff to ‘plead the who, what, when, where, and how’ of the allegedly fraudulent statements or omissions, though the ‘specific facts related to the defendant’s specific state of mind when the allegedly fraudulent statements were made’ need only be alleged generally.” *Aprigliano v. Am. Honda Motor Co.*, 979 F. Supp. 2d 1331, 1342 (S.D. Fla. 2013) (quoting *Mizzaro v. Home Depot, Inc.*, 544 F.3d 1230, 1237 (11th Cir. 2008)). Rule 9(b)’s heightened pleading standard also applies

to claims for negligent misrepresentation. *Lamm v. State St. Bank & Tr.*, 749 F.3d 938, 951 (11th Cir. 2014).

Plaintiff alleges she is only subject to a relaxed pleading standard because the requisite information was within Defendants' exclusive knowledge and control, the issues are complex, and the fraud occurred over an extended period. Doc. No. 34 at ¶¶ 51, 191, 212, 228. Rule 9(b)'s heightened pleading standard may be applied less stringently when specific factual information about the fraud is peculiarly within a defendant's knowledge or control. *Omnipol v. Worrell*, 421 F. Supp. 3d 1321, 1344 (M.D. Fla. 2019) (citing *Hill v. Morehouse Med. Assocs.*, No. 02-14429, 2003 U.S. App. LEXIS 27956, 2003 WL 22019936, at *3 (11th Cir. 2003)). However, to qualify for the more lenient standard, the information must be "in [the] exclusive control of the defendant and *cannot be possessed by other entities.*" (Emphasis added). *Davis v. Boston Sci. Corp.*, No. 2:17-cv-682, 2018 U.S. Dist. LEXIS 108141, at *12 (M.D. Fla. June 28, 2018) (quoting *Bray & Gillespie Mgmt. LLC v. Lexington Ins. Co.*, No. 6:07-cv-222, 2007 U.S. Dist. LEXIS 84305, 2007 WL 3457585, at *3 (M.D. Fla. Nov. 14, 2007)). There must not be alternative avenues for obtaining the information. *United States ex rel. Clark v. Tallahassee Surgical Assocs., P.A.*, No. 4:09-cv-411, 2010 U.S. Dist. LEXIS 155818, at *4 (N.D. Fla. Dec. 15, 2010). Even in those circumstances where the pleading standard can properly be relaxed, a plaintiff must still accompany her legal theories with factual allegations that

make the theoretically viable claim possible. *Davis*, 2018 U.S. Dist. LEXIS 108141, at *12. Conclusory allegations do not justify relaxation. *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1314 (11th Cir. 2002).

Here, Plaintiff generally alleges Defendants made misrepresentations or concealments that were relied upon by Davis's physicians, which proximately caused her injuries. Doc. No. 34 at ¶¶ 18-20, 44-48, 53-73, 173-75, 194-202. Plaintiff claims misrepresentations were made by retained key opinion leaders, agents, employees, representatives, or any other person acting on behalf of Defendants. *Id.* at ¶ 59. Plaintiff cites statements that the products were safe and effective, do not cause chronic conditions, and do not degrade or otherwise deform. *Id.* Plaintiff also cites the "substantial and particular fraud evidence that has been introduced [at] several pelvic mesh trials . . . which will be substantially similar if not identical to the evidence that will be introduced in this case, and the substantial general discovery . . . gives fair and specific notice of the alleged fraud herein." Doc. No. 34 at ¶¶ 192, 213, 229. Plaintiff alleges that it was "known or knowable" to Defendants that the TVT products caused large numbers of complications that were not rare and not caused by the surgical technique or training of the implanting surgeons. *Id.* at ¶ 194.

Plaintiff's allegations fail to provide the "who, what, when, where and how" of the fraud and misrepresentations she alleges in Counts VII, VIII, IX, and X.

Thus, her claims fail to satisfy Rule 9(b)'s heightened pleading standard. *See Merino*, 2021 U.S. Dist. LEXIS 84942, at *32 (dismissing fraud claims for plaintiff's failure to detail the "who, what, when, where, and how" of the fraud she alleges). The Court finds that her conclusory allegations, and the nature of her claims, also fail to support her assertion that a relaxed pleading standard is appropriate here. *See Davis*, 2018 U.S. Dist. LEXIS 108141, at *11-13 (finding stringency of Rule 9(b) relaxed when the information is in the exclusive control of the defendant and cannot be possessed by other entities, but difficulty in obtaining information as an outsider is not the same as the inability to do so). Plaintiff alleges the necessary evidence exists in other pelvic mesh cases, and that others have made misrepresentations on Defendants' behalf, including key opinion leaders, Doc. No. 34 at ¶¶ 38, 41, 59, 60, 192, 213, 229, which more than suggests information regarding the alleged fraud is not in the exclusive control of Defendants necessitating a relaxed pleading standard. Further, even if the relaxed standard was applied, Plaintiff still fails to provide sufficient factual allegations, instead opting for generalities and conclusory factual allegations. As such, the Court recommends Counts VII, VIII, IV and X be dismissed.

G. Count XII: Unjust Enrichment

Defendants argue that Plaintiff cannot maintain a claim for unjust enrichment because she fails to plead an "inequitable transfer of wealth" and she

is repackaging a tort claim. Doc. No. 39 at 20. Defendants also claim that Plaintiff cannot sufficiently plead that she lacks a legal remedy. *Id.* at 21.

Under Florida law, the elements of a claim for unjust enrichment are “(1) the plaintiff has conferred a benefit on the defendant; (2) the defendant voluntarily accepted and retained that benefit; and (3) the circumstances are such that it would be inequitable for the defendant to retain it without paying the value thereof.” *Virgilio v. Ryland Grp., Inc.*, 680 F.3d 1329, 1337 (11th Cir. 2012).

Plaintiff may plead unjust enrichment in the alternative. *See Merino*, 2021 U.S. Dist. LEXIS 84942, at *38. Plaintiff alleges Davis paid Defendants for the TVT products, that Defendants accepted payment for the TVT products, Davis did not receive the safe and effective TVT products she paid for, and it would be inequitable or unjust for Defendants to keep this money because Davis did not receive a safe and effective TVT product. Doc. No. 34 at ¶¶260-69. Thus, Plaintiff plausibly alleges a claim for unjust enrichment. *See Merino*, 2021 U.S. Dist. LEXIS 84942, at *39 (finding allegation plaintiff paid for safe product and failed to receive safe product plausibly stated a claim for unjust enrichment).

H. Leave to Amend

Plaintiff requests leave to amend if the Court determines that any legal deficiencies remain. Doc. No. 44 at 19-20. The Court finds that permitting leave to amend is appropriate under the circumstances.

IV. CONCLUSION.

Accordingly, it is **RECOMMENDED** that the Motion (Doc. No. 39) be **GRANTED in part** and **DENIED in part** as follows:

1. Counts III, V, VI, VII, VIII, IX, and X of the Second Amended Complaint be **DISMISSED without prejudice**;
2. Plaintiff be given leave to file an amended complaint within fourteen days of an Order adopting this Report and Recommendation;⁶ and
3. In all other respects, that the Motion be **DENIED**.

NOTICE TO PARTIES

A party's failure to file written objections to the proposed findings and recommendations contained in this report within fourteen days from the date of its filing waives the right to challenge on appeal the district court's order based on unobjected-to factual and legal conclusions.

RECOMMENDED in Orlando, Florida, on August 16, 2021.



GREGORY J. KELLY
UNITED STATES MAGISTRATE JUDGE

⁶ Failure by Plaintiff to file an amended complaint should result in conversion of the dismissal to one with prejudice.

Copies furnished to:

Presiding District Judge
Counsel of Record
Unrepresented Parties